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EXAMINER

KISHORE, G

ART UNIT

PAPER NUMBER

1615

6

DATE MAILED: 08/22/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on _____
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1- 33 is/are pending in the application.
Of the above, claim(s) 4- 21 & 25-33 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-3 & 22-24 is/are rejected.
- Claim(s) 4-21 & 25-33 is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
 received in Application No. (Series Code/Serial Number) _____
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 6
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

BEST AVAILABLE COPY

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Specification

1. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.
2. There are 8 Figures in the application and page 2 of the specification provides a brief description of the drawings to only two figures. The heading is also missing.

Claim Objections

2. Claims 4-21 and 25-33 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-21 and 25-33 have not been further treated on the merits.

Claims included in the prosecution are 1-3 and 22-24.

Claim Rejections - 35 U.S.C. § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposomes, does not reasonably provide enablement for claims recited in very vague confusing terms. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification is enabling for liposomes and nothing else. Broad claims must have broad basis of support in the specification; in the absence of such support, claims must be limited to liposomes.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First of all, independent claims are so confusing and it is unclear as to what is being claimed. They should be thoroughly revised and restructured.

'Membrane-like' in claims 1 and 22 and 'and the like' are indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

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'usually water' in claims 1 and 22 does not clearly and distinctly claim the subject matter. 'Especially' in claim 1 indefinite since it is unclear whether the limitation following these terms is indeed the limitation.

Regarding claim 22 (and many other dependent claims), the phrases "for example" (also in claim 23) and 'such as' render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

It is unclear as to what is being conveyed by 'otherwise controlled' in claim 24.

Claims 22-24 are method claims, but do not adequately and clearly recite the method steps. What is recited is very confusing.

The examiner suggests a careful revision of these claims and restructure the claims in accordance with US practice so that a meaningful search can be made.

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Claim Rejections - 35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0220 797 or Roberts (4,921,706) of record, or Mayer (BBA, 1986) of record, Blume (j. Of Liposome Research, 1992) of record, or EP 0 707 847 (Bayer) of record or EP 0 704 206 (Regenold) of record.

EP discloses liposomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation (note the abstract, column 1, examples and claims).

Similarly Roberts, Mayer, EP 847 and EP 206 all teach liposomes containing an amphiphilic lipid and a method of preparation (note the abstract and Materials & Methods section in both Roberts and Mayer; whole documents of EP).

Blume and EP 160 teach transfersomes and a method of preparation (note the entire documents).

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Claim Rejections - 35 U.S.C. § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-3 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 220 797, or Roberts (4,921,706) of record, or Mayer (BBA, 1986) of record, Blume (J. Of Liposome Research, 1992) of record, or EP 0 707 847 (Bayer) of record or EP 0 704 206 (Regenold) of record.

As pointed out above, the references teach liposomes or transfersomes containing a drug, an amphiphilic lipid and a surfactant in instant amounts and a method of preparation. It is unclear whether the references teach all the instant functional parameters. In case they are different, in the absence of showing the criticality, they are deemed to be parameters manipulatable by an artisan to obtain the best possible results.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to G.S. Kishore whose telephone number is (703) 308-2440.

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The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

August 21, 2000